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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/554,259

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Mitsuo Ochi

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EXAMINER

BURK, CATHERINE E

ART UNIT

PAPER NUMBER

3735

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/554,259	Applicant(s) OCHI, MITSUO	
	Examiner CATHERINE E. BURK	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>25 October 2005, 3 August 2006, 6 September 2006, 9 November 2006, 30 July 2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claim 5 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 5 states "wherein the particle comprises at least a magnetic material" however claim 1 states "a magnetic cell, comprising a magnetic particle..." A magnetic particle must comprise a magnetic material.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 8-10 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: how the magnetic cell is cultured.

5. The term "long time" in claim 9 is a relative term which renders the claim indefinite. The term "long time" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear for how long the magnetic cell is retained by means of a magnetic field at a disease site.

Art Unit: 3735

6. Claim 13 recites "a method for treating" but it is not clear what the method is treating.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-5 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Margolis (Biochimica et Biophysica Acta. 735: 193-195, 1983).

9. Regarding claims 1-5; Margolis discloses a cell comprising a ferromagnetic particle (claim 5) in the form of an immunomagnetoliposome attached to the surface of the cell (claim 1) via a chemical bond (claim 4) formed by an antigen-antibody linker (claims 2 and 3) (page 193, left column, lines 7-18).

10. Regarding claim 8; Margolis also discloses a method of preparing the magnetic cell (page 194, left column, first full paragraph) and culturing the magnetic cells (page 194, right column, lines 1-12).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Margolis in view of Kubo (International Journal of Oncology. 17: 309-315, 2000).

13. Regarding claim 6; Margolis fails to disclose the magnetic particle also comprises a drug. However, Kubo discloses magnetic liposomes containing the anticancer drug adriamycin (ADR) and it would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the drug-containing magnetic liposomes disclosed by Kubo for the magnetic liposomes used for cell sorting disclosed by Margolis. Doing so would allow a user to selectively sort and deliver drugs that are normally toxic to healthy organs, to only cancerous tissue.

14. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Margolis in view of Bates (The Journal of Biological Chemistry 266(28) 18593-18599, 1991).

15. Regarding claim 7; Margolis discloses the cells are mouse embryo fibroblasts and Bates discloses that embryonic fibroblasts, such as the cells used by Margolis, are integrin-expressing cells (page 18594, left column, Experimental Procedures, Cells). It would have been obvious to one of ordinary skill in the art at the time of the invention that the embryonic fibroblasts of Margolis are integrin-expressing cells, as expressly taught by Bates.

16. Claims 9-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kubo in view of Margolis.

17. Regarding claims 9 and 10; Kubo discloses a method of moving a cancer drug-containing magnetic liposome (claims 12 and 14) to a disease site and retaining the liposome within the disease site for the duration of treatment by applying an external magnetic field or implanting a

Art Unit: 3735

magnet inside the body (claims 9 and 10) (page 314 left column, bottom paragraph). The drug is released from the magnetic liposome gradually to the tumor interstitium and surrounding tumor cells (page 314, right column, lines 12-4). Kubo fails to disclose the magnetic liposome is linked to a cell.

18. However, Margolis discloses linking a magnetic liposome to a cell in order to facilitate cell sorting. It would have been obvious to one of ordinary skill in the art at the time of the invention that linking the magnetic liposomes disclosed by Kubo to the cells disclosed by Margolis and simultaneously delivering the cell-liposome complex to a disease site would improve the method disclosed by Kubo because it would improve the retention of the drug-containing liposome at the targeted cell site via antigen/antibody bonds with the target cells.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following references are cited for disclosing related limitations of the applicant's claimed and disclosed invention. Gordon (US 4106488 A) discloses treating cancerous cells by introducing magnetic particles into cells and applying electromagnetic energy to generate heat in the magnetic particles to selectively kill the cancer cells only. Gudov (US 5067952 A) discloses a method of treating tumors by guiding a suspension of ferromagnetic particles and retaining the particles with the aid of a magnetic field and exposing the area to an electromagnetic field to carry out hyperpyrexia of the tumor.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHERINE E. BURK whose telephone number is (571) 270-7130. The examiner can normally be reached on Monday-Thursday 8:30 AM - 6:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles A. Marmor II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charles A. Marmor, II/
Supervisory Patent Examiner
Art Unit 3735

/C. E. B./
Examiner, Art Unit 3735